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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,010	09/15/2003	Tim Clarot	33205.0800	1757

20322 7590 08/11/2009

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	
MAIL DATE	**DELIVERY MODE**
08/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,010	CLAROT ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30,31 and 40-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,31 and 40-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 30-31 and 40-57 are pending. Applicant previously cancelled claims 1-29, and 32-39. Applicants amended claims 30-31, 40-46, and 57. Receipt and consideration of Applicants' claim amendments and remarks/arguments, submitted on May 13, 2009 are acknowledged. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments. Applicants' claim amendments have necessitated new grounds of rejection set forth below (e.g. 35 U.S.C. § 112, 2nd paragraph).

Claim Interpretation[1]

At the outset, the following claim interpretation is set forth so that the grounds of rejection hereinafter can be better understood. There is one independent claim and many dependent claims in the instant application that explicitly describe the **composition viscosity**:

• Wherein the composition has a viscosity of about 2,500 cp and to about 40,000 cp (independent claims 30-31, 41, and claims dependent therefrom).

The one thing that stands out about applicant's choice of claim language is that the viscosity numbers are provided without a temperature parameter. Viscosity of a fluid is of course known to change with temperature. Common experience of every person who has spent any time in the kitchen is that a fluid such as a hot sauce, chocolate melt or gravy thickens (viscosity increases) when cooled (as temperature decreases). McGraw-Hill Encyclopedia of Science & Technology discloses, inter alia, that the viscosity of glycerin1 at 0°C is 12,110 cp, and MacMillan Encyclopedia of Physics discloses that the viscosity of glycerin changes

dramatically as the temperature increases: 830 cp (20°C), 0.16 cp (40°C) and 0.044 cp (60°C). Hence, within a temperature difference of 60°C, viscosity of glycerin can change by a factor of 275,227.

Plainly, viscosity of a fluid cannot have a fixed meaning without its temperature. Therefore, applicant's failure to specify a temperature for the claimed viscosity feature is interpreted as leaving open the viscosity as a feature that can exist at any temperature. For example, glycerin per se would meet all of applicant's claimed viscosity feature language as set forth above, because it inherently does possess a viscosity within 2500-40,000 cp since its viscosity at 0°C is 12,110 cp.

The term "extended time" is not defined in Applicants' specification. This term is reasonably interpreted to refer to any time periods that are not instantaneous (i.e. extended).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter). The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' amendments to claims 30-31 introducing a range of the amount

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[1] This claim interpretation is also applied to copending applications and commonly owned U.S. Patents cited below in the obviousness-type double patenting section.

of thickener of "about 0.000001 to about 5.0 wt. %" introduces new matter, because Applicants' specification (see paragraph [0033]) only has support for thickener amounts of 0.000001 to 5.0 wt.%. The introduction of the word "about" before the two endpoints of the supported range effectively expands the scope of the recited range outside of what is present in Applicants' specification. Thus, the range of thickener as recited in claims 30-31 is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-31 and 40-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' amendments to claims 30-31 and 41-45 to include a description of the recited viscosity values as being measured according to ASTM D1824-87 renders these claims indefinite, because "ASTM D1824-87" is unknown. ASTM numbers are assigned by the American National Standards Institute (ANSI) for various standards associated with different materials and methods. A search of the ANSI website for the ASTM number recited in Applicants' claims yielded zero hits. Thus, an ordinary skilled artisan would be unable to ascertain the meaning of "ASTM D1824-87" and would be unable to measure viscosity according to this publicly unknown standard, making claims 30-31 and 41-45 indefinite.

Claim 40 is indefinite because it now claims a composition comprising at least one vitamin in an amount "less than about 5.0% by weight." The phrase "less than about" is indefinite, because it simultaneously claims two different ranges. An ordinary skilled artisan

would be unable to ascertain whether the required amount of vitamin is less than 5.0% w/w or about 5.0% w/w. It is also noted that the term about refers to a dynamic range and less than refers to a static range. Thus, the phrase "less than about" also results in uncertainty in the required metes and bounds of said claim, because the maximum endpoint is ambiguous. Appropriate correction is required.

Claim 57 is indefinite, because it is unclear what time period would constitute "an extended period of time," and Applicants' specification does not define the phrase "extended period of time." Therefore, an ordinary skilled artisan would be forced to guess what time periods were encompassed by the recited step of maintaining the composition in contact with the nasal membrane.

The remaining claims are rejected as depending from a rejected claim.

Response to Arguments

Applicant's arguments with respect to claims40-41 and 40-57 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haslwanter et al. (U.S. Patent No. 6,565,832) in view of Sundgreen et al. (U.S. 2002/0147232).

Applicant Claims

Applicants claim a composition for application to a nasal membrane to reduce symptoms associated with allergies and the common cold comprising (i) about 90-99.999 % w/w carrier, (ii) about 0.000001 to about 5.0 wt.% thickener comprising one or more compounds selected from the group consisting of glycerin, carrageenan, sugar, guar gum, methyl cellulose, and hydroxycellulose, (iii) about 0.001 to about 5.0 % w/w at least one active agent comprising oxymetazoline hydrochloride, and (iv) about 0.00001 to about 5.0 % w/w of a permeation enhancer comprising liposomes, wherein the composition has a viscosity between about 2,500 to about 40,000 centipoise, as measured according to "ASTM D1824-87," wherein the composition is a gelled matrix.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Haslwanter teaches aqueous nasal compositions comprising a therapeutic or palliative agent, water, and a mixture of microcrystalline cellulose, and alkali metal carboxyalkylcellulose, wherein in one embodiment the nasal spray exhibits a very rapid viscosity recovery upon removal of shear forces (title; abstract; Figure 1; col. 2, lines 16-32). Haslwanter's Examples 3D-3G (col. 6, line 50 through col. 7, line 13) disclose compositions comprising (a) **~88-95% w/w water (carrier), (b) 0.0488 % w/w oxymetazoline hydrochloride, (c) ~2.44-2.93 % w/w AVICEL-591 (an 89:11 mixture of microcrystalline cellulose and sodium carboxymethylcellulose; thickener), (d) about 0-3% w/w PVP, (e) about 0-4.9% PEG-32 (emulsion agent), (f) about 0.095 % w/w sodium phosphate dibasic (buffer), (g) about 0.54% w/w sodium phosphate dibasic (buffer), (h) about 0.029% w/w disodium EDTA (permeation enhancer, sequestering agent, and preservative), (i) about 0.14% w/w of a 17% aq. benzalkonium chloride solution (preservative), (j) about 0.24% w/w benzyl alcohol (preservative)**, and (k) about 0.146% w/w lemon flavor.

The compositions generally comprise **at least about 2.5% of cellulose/carboxyalkylcellulose mixture** (thickener), preferably about 2.5-3.5% w/w (col. 3, lines 56-64). The compositions generally have a pH of about 4 to about 8 and may comprise buffering substances, such as phosphate or citrate buffer systems (col. 4, lines 14-19). The compositions may also comprise up to 10% w/w, preferably 0.5-5% w/w of a rheology-modifying agent (i.e. thickener), such as sodium carboxymethyl cellulose, algin, **carageenans, hydroxypropyl cellulose, polyethylene glycols, dextran**, or combinations of two or more such agents (col. 4, lines 25-32). The composition **may further comprise additional humectants (e.g. glycerin [also known as glycerol], PEG, or other glycols), preservatives (e.g. benzyl**

alcohol, parabens, and benzalkonium chloride), and aromatic substances (e.g. camphor, menthol, and eucalyptol) (col. 4, lines 33-46). The amount of **cellulose/carboxyalkylcellulose mixture and other rheology modifiers can be varied to obtain a desired viscosity behavior** (col. 5, lines 10-15).

Sundgreen teaches that liposomes are conventional carriers [0206] and that liposomes are expected to enhance penetration (i.e. enhance permeation) of active agent into the mucosa, such as the nasal mucosa [0604].

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Haslwanter lacks the teaching of decongestant compositions comprising liposomes. This deficiency is cured by the teachings of Sundgreen. Haslwanter lacks the teaching of an explicit viscosity value for the invented compositions. The selection of a particular viscosity is obvious as explained below.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person or ordinary skill in the art at the time of the instant invention to combine the teachings of Haslwanter and Sundgreen, because Haslwanter teaches nasal compositions that would benefit from the inclusion of mucosal/nasal penetration enhancers, such as liposomes. An ordinary skilled artisan would have been motivated to include liposomes in Haslwanter's invented compositions to enhance the uptake of the active ingredient (e.g. oxymetazoline hydrochloride) present in Haslwanter's compositions. An ordinary skilled

artisan would have had a reasonable expectation that the inclusion of liposomes would successfully enhance the permeation or penetration of active agent in Haslwanter's compositions, because the art explicitly suggests that liposomes would enhance penetration of active ingredient in mucosal tissues, such as nasal mucosa.

Regarding the composition viscosity, it is the Examiner's position that Haslwanter's invented compositions necessarily have a viscosity meeting the limitations of Applicants' claims 30-31, because the amount of thickener in Haslwanter's compositions is within the range disclosed by Applicants as corresponding to a viscosity range of about 2,500 cp to about 40,000 cp as evidenced by Applicants' claims 40 and 41. Furthermore, Haslwanter's exemplified compositions are characterized as being "no-drip", as evidenced by Haslwanter's Figure 1. Haslwanter's exemplified composition of Example 5 (Figure 2) exhibited a viscosity of 10-1,000 for about 5 seconds (i.e. an extended period of time) under dynamic stress experimental conditions. Assuming that the units of viscosity in Haslwanter's figure 2 are dyne*s/sq. cm, then this corresponds to a viscosity of 1,000 to 10,000 centipoise. Finally, it is art recognized that varying the amount of thickener and other rheology modifiers in a composition varies the compositions viscosity. Because the amount of a composition ingredient, such as a thickener, is a result effective parameter, viscosity is also a result effective parameter, wherein the amount of thickener is varied. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments filed May 13, 2009 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection by arguing that (1) an ordinary skilled artisan would not have combined the teachings of Sundgreen and Haslwanter, because Haslwanter's composition comprises EDTA (a permeation enhancer) and an ordinary skilled artisan would not add another different permeation enhancer to Haslwanter's composition; (2) allegedly *Ex Parte Rinkevich* (BPAI 2007-1317) supports Applicants' position that an ordinary skilled artisan would not be motivated to add additional permeation enhancers to Haslwanter's composition; (3) allegedly it is unobvious to utilize the specific thickeners recited in Applicants' claims to modify composition viscosity; (4) it is allegedly unobvious to modify the amount of a known thickeners, because each thickener has different and distinct properties; and (5) the active agent utilized in Sundgreen is desglymidodrine, a vasopressor, which is functionally different from the active agent required by Applicants' claims.

Applicants' arguments are respectfully found unpersuasive. Regarding (1)-(2), it is prima facie obvious to combine two compounds known in the art to have the same utility. It is generally considered *prima facie* obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See *In re Kerkhoven*, 626, F.2d 848, 205 USPQ 1069 (CCPA 1980). Furthermore, it is noted that EDTA is art-recognized as having multiple properties, such as a preservative and permeation enhancer. Thus, the mere fact that Haslwanter's composition

comprises EDTA is not evidence that an ordinary skilled artisan would conclude that it would be unnecessary or even undesirable to add another known permeation enhancer, such as liposomes.

Specifically, regarding (2), *Ex Parte Rinkevich* is a ***non-binding, non-precedential, unpublished*** BPAI decision, and as such does not reflect the state of the law or impose a required interpretation of the law. Thus, reliance on *Ex Parte Rinkevich* does not make Applicants' arguments persuasive. Arguments (1)-(2) are unpersuasive.

Regarding (3)-(4), Haslwanter explicitly identifies carrageenan as an additional rheology-modifying agent (i.e. thickener) that may be added to the composition in amounts of up to 10% w/w. Thus, the amount of carrageenan and other thickeners taught by the combined references overlaps with the amounts recited in Applicants' claims. It is noted that an amount of about 5.0 wt. % reasonably reads on 10 wt. %, because Applicants have not defined the term "about" to have a specific meaning. Furthermore, it is known that the amount of thickener can be adjusted to adjust the viscosity of a composition. Use of a thickener or other known rheology modifying agent to modify the viscosity (i.e. rheology) is obvious. It is not inventive to use a thickener to thicken or modify the viscosity of a composition. In fact it is predictable and expected that addition of a thickener to a composition will change the composition viscosity and that greater amounts of thickener will result in higher composition viscosities at a given temperature. Applicants' arguments are unpersuasive.

Regarding (5), in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Moreover, it is

reiterated that Sundgreen was provided as an evidentiary reference to demonstrate that liposomes are art-recognized permeation enhancers. Thus, the fact that Sundgreen's compositions utilize a different active agent than Haslwanter is not relevant, because Sundgreen establishes that it was well known in the art to use liposomes as permeation enhancers. The rejection remains proper and is maintained.

Claims 40-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haslwanter et al. (U.S. Patent No. 6,565,832) in view of Bates (U.S. Patent No. 4,826,683), as evidenced by Schulte (U.S. Patent No. 4,708,873), Mundschenk (US 2004/0197270), and Estell et al. (U.S. Patent No. 6,929,939).

Applicant Claims

Applicants claim a composition for application to a nasal membrane to reduce symptoms associated with allergies and the common cold comprising (i) about 90-99 % w/w water, (ii) about 0.045 to about 0.055 % w/w oxymetazoline hydrochloride, (iii) about 0.00001 to about 5.0 % w/w of a permeation enhancer, (iv) about 0 to about 1.0 wt % aromatic substance selected from the group consisting of camphor, eucalyptus oil, menthol, azulen, extracts thereof or mixtures thereof, (v) about 0.001 to about 1.0 % w/w preservative, (vi) about 0.000001 to about 5.0% w/w thickener, (vii) 0.05% to about 5.0% glycerin, (viii) about 0.00001 to about 1.0% w/w emulsion agent, (ix) about 0.0002 to about 6.0% w/w buffer, and (x) less than about 5.0% w/w of at least one vitamin.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Haslwanter have been set forth above.

Bates teaches **decongestant compositions in the form of nasal spray** that are designed to be applied to the nasal passages comprising **about 0.1-5.0 g/L (i.e. ~0.0001-0.005% w/w) aloe vera (i.e. aloe barbadensis gel)**, about 10-1,000 mg/L vitamin C (i.e. ~0.00001-0.001 % w/w), zinc, carriers, solvent, etc. (title; abstract; col. 1, lines 1-6 and 55-68; col. 2, lines 48-64; and claims 1-7). The aloe in Bates' compositions is either aloe juice or aloe vera gel, **preferably aloe vera gel**. Bates also teaches that **any source of aloe vera may be used** (col. 2, lines 48-49).

Schulte teaches that aloe vera stimulates wound healing and inhibits the formation of granulation tissue (col. 1, lines 53-57).

Mundschenk demonstrates that aloe vera powder is a known source of aloe vera ([0093]).

Estell evidences that **aloe vera in any of its variety of forms is a known humectant** (co. 27, lines 29-38, especially lines 33-34).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Haslwanter lacks the teaching of decongestant compositions comprising aloe barbadensis gel. This deficiency is cured by the teachings of Bates. Haslwanter lacks the teaching of compositions comprising hydroxyethylcellulose. Hydroxyethyl cellulose is a well-known conventional thickener, as admitted by Applicants (see page 6 of Applicants' remarks submitted 7/30/08, which is the 1st page of Applicants' arguments).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person or ordinary skill in the art at the time of the instant invention to modify the compositions of Haslwanter to include aloe vera gel (i.e. aloe barbadensis gel), because aloe vera gel is a conventional ingredient in nasal spray formulations (Bates) that promotes healing (Schulte). An ordinary skilled artisan would have been motivated to include aloe vera in any of its variety of forms (e.g. gel or powder) in Haslwanter's invented compositions, because it is a conventional ingredient in nasal formulations that can also stimulate healing, is known to act as a humectant, and Haslwanter explicitly suggests the inclusion of humectants. An ordinary skilled artisan would have had a reasonable expectation of successfully preparing nasal spray compositions comprising aloe vera powder, because Bates teaches that any source of aloe vera may be used in nasal sprays; aloe vera powder is a known source of aloe vera (Mundschenk); and Estell teaches that aloe vera in any of its various forms is a known humectant. Furthermore, Bates teachings establish that aloe vera is a conventional ingredient of known nasal spray compositions.

Regarding the recitation of at least one vitamin in an amount of less than about 5.0%, Bates teaches that nasal spray compositions may comprise about 10-1,000 mg/L vitamin C (i.e. ~0.00001-0.001 % w/w), which meets Applicants' new claim limitation.

Regarding the composition viscosity, it is the Examiner's position that Haslwanter's invented compositions necessarily have a viscosity meeting the limitations of Applicants' claims 41-47, because the amount of thickener in Haslwanter's compositions is within the range disclosed by Applicants as corresponding to a viscosity range of about 2,500 cp to about 40,000 cp as evidenced by Applicants' claims 40 and 41. Furthermore, Haslwanter's exemplified

compositions are characterized as being "no-drip", as evidenced by Haslwanter's Figure 1. It is art recognized that varying the amount of thickener and other rheology modifiers in a composition varies the compositions viscosity. Because the amount of a composition ingredient, such as a thickener, is a result effective parameter, viscosity is also a result effective parameter, wherein the amount of thickener is varied. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics such as **viscosity.** When as here, the prior art appears to contain the same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Regarding the amounts of the other composition ingredients (e.g. buffering compounds), the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments filed May 13, 2009 have been fully considered but they are not persuasive. Applicants' traversal arguments related to the alleged deficiencies of the combination of Haslwanter and Sundgreen have been rebutted above. The rebuttal of these arguments is herein incorporated by reference. Applicants' have additionally traversed the instant rejection by arguing that (1) the cited references allegedly require the inclusion of components that materially affect the basic and novel characteristics of the claimed composition, such as Applicants' allegation that different thickeners have different thickening properties and the presence of microcrystalline cellulose an alkali metal carboxyalkylcellulose would materially affect the claimed composition's thickening properties; (2) it is allegedly not obvious to include aloe vera, which is known to be a suitable component of nasal sprays (Bates), because Schulte identifies aloe vera as having wound healing properties; and (3) Haslwanter and Bates allegedly provide no reason for including aloe vera in nasal compositions containing a nasal decongestant.

The Examiner respectfully finds Applicants' arguments unpersuasive.

Regarding (1), it is incumbent upon Applicants to provide a side-by-side comparison, such as with data presented in a 1.132 declaration, demonstrating that the additional components in Haslwanter (e.g. microcrystalline cellulose an alkali metal carboxyalkylcellulose) materially affect the basic and novel characteristics of Applicants' claimed composition. In fact the courts have held that it is Applicants' burden to demonstrate that additional components materially affect claimed subject matter. See MPEP § 2105. Attorney argument in the absence of objective evidence is unpersuasive. It is also noted that Applicants' claims recite an extremely broad viscosity range and their claims also do not specify a temperature at which the claimed

compositions exhibit the recited viscosity. See comment above about the claim interpretation applied herein to the art rejections.

Regarding (2), Bates establishes that aloe vera is a conventional ingredient in nasal sprays. Applicants are claiming a nasal composition, thus, one would look to Bates for guidance regarding components that are suitable for inclusion in nasal compositions. Bates inclusion of aloe vera in nasal spray compositions is a clear indication that it is a conventional ingredient of nasal spray compositions. Applicants' argument is unpersuasive.

Regarding (3), aloe vera is a well known humectant (Estell). Haslwanter clearly teaches that it is desirable to include humectants (col. 4, lines 33-46), and aloe vera is known to be suitable for use in nasal sprays (Bates). Applicants' argument is unpersuasive. The instant rejection is maintained.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ebert (U.S. Patent No. 7,029,694) is considered relevant, because it establishes that aloe vera is a known emollient (col. 19, lines 55-61).

Claims 30-31 and 40-57 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner is on a flexible schedule, but can normally be reached on M-F ~10am~5:30 pm, and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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